K083178

DEC 22 2008

**510(k) Summary**
**Prepared August 27, 2008**
**Revised December 18, 2008**


**Sponsor:** Siemens Medical Solutions USA, Inc.,
Ultrasound Division
1230 Shorebird Way
P.O. Box 7393
Mountain View, California 94039-7393

**Contact Person:** Sheila W. Pickering Ph.D.
Telephone: (650) 943 7187
Fax: (650) 943 7053


**Submission Date:** April 18, 2008

**Device Name:** Acuson S2000 ABVS Ultrasound System

**Common Name:** Diagnostic Ultrasound System with Accessories

**Classification:**
Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology

| | | |
|---|---|---|
| Ultrasonic Pulsed Doppler Imaging System | FR # 892.1550 | Product Code 90-IYN |
| Ultrasonic Pulsed Echo Imaging System | FR # 892.1560 | Product Code 90-IYO |
| Diagnostic Ultrasound Transducer | FR # 892.1570 | Product Code 90-ITX |

**A. Legally Marketed Predicate Devices**
The Acuson S2000 ABVS Ultrasound system is substantially equivalent to the Acuson S2000 ultrasound system (K072786)and the U-Systems ultrasound system..

**B. Device Description:**

The Acuson S2000 ABVS Ultrasound System has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- **AIUM/NEMA UD-3, 1998 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment**
- **AIUM/NEMA UD-2, 1998 Acoustic Output Measurement Standard for Diagnostic Ultrasound**
- 93/42/EEC Medical Devices Directive
- **Safety and EMC Requirements for Medical Equipment**
  - **EN/IEC 60601-1**
  - **EN/IEC 60601-1-1**
  - **EN/IEC 60601-1-2**
- **IEC 1157 Declaration of Acoustic Power**
- **ISO 10993-1 Biocompatibility**

**C. Intended Use**

The Modified S2000, the S2000 ABVS Ultrasound System, is intended for the following applications: General Radiology, Abdominal, Fetal, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Pediatric, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications. The system supports the transducers listed in the Ultrasound Indications for Use tables, including the 14L5BV for B-mode imaging of a patient's breast using an optional automatic scanning function. The device is not intended to be used as a replacement for screening mammography.

The system also provides for the measurement of anatomical structures and analysis as provided in the original S2000 Ultrasound System, which provides information that is used by medical health care professionals for clinical diagnosis purposes.

**D. Substantial Equivalence**

The submission device is substantially equivalent to the predicate devices with regard to both intended use and technological characteristics.

**E. Performance Data**

The S2000 modifications are verified and validated according to the company's design control process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 16 2009

Ms. Shelly Pearce
Regulatory Affairs
Siemens Medical Solutions USA, Inc.
Ultrasound Division
1230 Shorebird Way
MOUNTAIN VIEW WAY CA 94043-1344

Re: K081148
Trade/Device Name: Acuson S2000 ABVS Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: November 21, 2008
Received: November 26, 2008

Dear Ms. Pearce:

This letter corrects our substantially equivalent letter of December 22, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson S2000 ABVS Ultrasound System, as described in your premarket notification:

Transducer Model Number

CW2 Probe
CW5 Probe
EC9-4 Curved Array
9L4 Linear Array
14L5 Multi-D Array
4P1 Phased Array
6C2 Curved Array
4C1 Curved Array
4V1 Phased Array

10V4 Phased Array
14L5 SP Linear Array
7CF2 Curved Array Mechanical 3D
9EVF4 Curved Array
V5Ms Multiplane TEE
18L6HD Linear Array
8V3 Phased Array
14L5BV Multi-D Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K081148

Device Name: *ACUSON S2000 ABVS Ultrasound System*

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11, 13 |
| Abdominal | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11, 13 |
| Intraoperative (Note 9) | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11, 14 |
| Intraoperative Neurological | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11, 14 |
| Pediatric | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11 |
| Small Organ (Note 1) | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11,14 |
| Neonatal Cephalic | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10 |
| Adult Cephalic | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10 |
| Cardiac | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,6,7,8,10 |
| Trans-esophageal | | P | P | P | P | P | P | | BMDC | |
| Transrectal | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11,14 |
| Transvaginal | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11 |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | P | P | P | | BMDC | Note2,3,4,5,6,7,8, 10, 11,14 |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11,14 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Musculo-skeletal Superficial | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11,14 |
| Other (specify) Neonatal Cardiac | | P | P | P | P | P | P | | BMDC | Note 3,4,6 |

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:
Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 9 For example: vascular, abdominal
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear multi-view spatial compounding
Note 13 STIC
Note 14 eSie™ Touch elasticity imaging/FTI

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K081148

## Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

*14L5BV Multi-D Array Transducer for use with ACUSON S2000 ABVS*

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
| ***Ophthalmic*** | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (Note 1) | | N | | | | | | | | Note 2,3,4,5,7,8,10, 11, 14 |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K# 063085; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear multi-view spatial compounding
Note 14 eSie™ Touch elasticity imaging/FTI

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K081148